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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,174	08/28/2003	J. Wallace Parce	100/06341	5968
21569	7590	11/30/2005	EXAMINER	
CALIPER LIFE SCIENCES, INC. 605 FAIRCHILD DRIVE MOUNTAIN VIEW, CA 94043-2234			TRAN, MY CHAU T	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/650,174	Applicant(s) PARCE ET AL.	
	Examiner MY-CHAU T. TRAN	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/28/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application and Claims Status

1. Applicant's response filed 09/12/2005 is acknowledged and entered.
2. Claims 1-28 are pending.

Election/Restrictions

3. Applicant's election without traverse of Group I (Claims 1-27) in the reply filed on 09/12/2005 is acknowledged.
4. Claim 28 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a *nonelected invention*, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09/12/2005.

Priority

5. This instant application is a DIV of 09/579,111 filed 05/25/2000, which claims benefit to four provisional applications. The provisional applications are 60/191,784 filed 03/24/2000, 60/176,093 filed 01/14/2000, 60/176,001 filed 01/12/2000, and 60/155,259 filed 06/01/1999. This instant application is granted the benefit of priority for 09/579,111 under 35 U.S.C 120 and for all four provisional applications under 35 U.S.C 119(e), which are 60/191,784, 60/176,093, 60/176,001, and 60/155,259.

Information Disclosure Statement

The information disclosure statements (IDS) filed on 08/28/2003 have been reviewed, and its references have been considered as noted on PTO-1449 forms. *Note: Applicant indicated that copies of the documents were submitted in the application of 09/579,111.*

Specification

6. Although the instant specification does refer to the prior application, it did not include the status of the prior application. Applicant is reminded that the specific reference to the earlier filed application must be made in the instant application, i.e. ***a reference to the prior application must be inserted as the first sentence(s) of the specification*** of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). This should appear as the first sentence(s) of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. ***Also, the current status of all nonprovisional parent applications referenced should be included.***

The instant specification needs to include the status of the prior application 09/579,111, which is now a patent, i.e. US Patent 6,649,358. In addition, the reference to the prior applications is not inserted as the first sentence(s) of the specification. Appropriate correction is required.

Art Unit: 1639

7. Claims 1-27 are under consideration in this Office Action.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. *The instant invention recites a method of detecting a binding activity. The method comprises the steps of a) flowing a first component or a set of first components through a first channel concomitant with a second component or a set of second components through the first channel; b) the second component or the set of second components binds to the first component or the set of first components; and c) detecting a detectable signal that indicates a final concentration of the at least one first component or the set of first components that remains unbound after exiting from the first channel, thereby detecting the binding activity.*

The limitation that first channel comprises a mixing longitudinal segment is interpreted as a structural limitation of the first channel.

The limitations that the first component or the set of first components 1) diffuses more rapidly in solution than the at least one second component or the set of second components, and 2) diffuses substantially across the first channel in the mixing longitudinal segment are interpreted as functional limitations of the first component or the set of first components.

The limitation that the second component or the set of second components diffuses less than substantially across the first channel in the mixing longitudinal segment is interpreted as functional limitation of the second component or the set of second components.

10. Claims 1, 3, 13-15, 18-20, 21, 23, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Yager et al. (US Patent 5,716,852).

Yager et al. disclose a system and methods for detecting the presence of analyte particles in a sample stream (see e.g. Abstract; col. 1, lines 10-16; col. 3, lines 17-36; col. 5, lines 38-54). In one type method disclosed by Yager et al., the method comprises the steps of 1) conducting the sample (refers to instant claimed second component) stream and an indicator (refers to instant claimed first component) stream into a laminar flow channel (refers to instant claimed first channel) such that the sample stream and indicator stream flow in adjacent laminar streams in the laminar flow channel (refers to instant claimed step (a)); 2) allowing the analyte particles of the sample stream to diffuse into the indicator stream such that the analyte particles causes a detectable change in property of the indicator substance in the indicator stream (refers to instant claimed step (b) and instant claimed functional limitations of the first and second components); 3) detecting the concentration of the analyte by measuring the signal of the indicator stream before and after diffusion of the analyte particles into the indicator stream (refers to instant claimed step (c) and instant claim 21)(see e.g. col. 3, lines 5-16, and 50-67; col. 5, line 39 thru col. 6, line 20; col. 10, lines 34-42) . The diffusion of the analyte particles into the indicator stream is perpendicular to the flow of the direction (see e.g. col. 7, lines 53-61). The sample stream comprises analyte particles such as blood cell (refers to instant claim 15) and the molecular weight of less than 1,000,000 MW (refers to instant claims 18 and 19)(see e.g. col. 4, lines 4-19). The indicator stream comprises indicator substance such as organic molecule (refers to instant claim 3)(see e.g. col. 3, lines 50-67; col. 4, lines 20-31). The laminar flow channel comprises a length to permit small analyte particles to diffuse from the sample stream and a depth to allow flow of two streams (refers to instant structural limitations of the first channel and instant claim 23)(see e.g. col. 4, lines 49-67). The detection signal includes fluorescence (refers

Art Unit: 1639

to instant claim 27)(see e.g. col. 3, lines 50-67). The fluid flow through the device comprises means for applying pressure to the flow of the fluid (refers to instant claim 20)(see e.g. col. 10, lines 5-19).

Additionally, the features of remaining dependent claims, i.e. claims 13 and 14, are either specifically described by the reference (e.g. diffusion coefficient, see e.g. col. 10, lines 44-51), or constitute obvious variations in parameters which are routinely modified in the art, and which have not been described as critical to the practice of the invention.

Therefore, the system and method of Yager et al. anticipates the presently claimed invention.

11. Claims 1, 3, 13-15, 20, 23, and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Wu et al. (US Patent 6,221,677 B1; *effective filling date of 09/26/1997*).

Wu et al. disclose apparatus and methods for detecting the presence of analyte particles in a sample fluid (see e.g. Abstract; col. 1, lines 11-17, and 54-62; col. 2, lines 45-56). In one type method disclosed by Wu et al., the competitive immunoassays method comprises the steps of 1) flowing the sample stream containing native antigens (refers to instant claimed second component and instant claim 15) and the reagent stream containing antibodies bound to fluorescently labeled antigen (refers to instant claimed first component and instant claim 3) into a laminar flow channel (refers to instant claimed first channel) such that the sample stream and indicator stream flow in adjacent laminar streams in the reaction channel (refers to instant claimed step (a)); 2) allowing the native antigens to diffuse into the reagent stream and displace the fluorescently labeled antigens (refers to instant claimed step (b) and instant claimed

Art Unit: 1639

functional limitations of the first and second components); 3) detecting the amount of free and bound fluorescently labeled antigens (refers to instant claimed step (c))(see e.g. col. 2, lines 45-56; col. 6, lines 14-23; col. 7, lines 31-46). The laminar flow channel comprises a length to permit small analyte particles to diffuse from the sample stream and a depth to allow flow of two streams (refers to instant structural limitations of the first channel and instant claim 23)(see e.g. col. 12, lines 31-39). The detection signal includes fluorescence (refers to instant claim 27)(see e.g. col. 2, lines 45-56; col. 6, lines 34-50). The fluid flow through the device comprises means for applying pressure to the flow of the fluid (refers to instant claim 20)(see e.g. col. 12, lines 40-49).

Additionally, the features of remaining dependent claims, i.e. claim 13 and 14, are either specifically described by the reference (e.g. diffusion coefficient, see e.g. col. 10, lines 44-51), or constitute obvious variations in parameters which are routinely modified in the art, and which have not been described as critical to the practice of the invention.

Therefore, the system and method of Wu et al. anticipates the presently claimed invention.

12. Claims 1-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Parce et al. (US Patent 6,274,337 B1; *filling date of 03/19/1998*).

Parce et al. disclose microfluidic devices and methods for performing high-throughput screening assays (see e.g. Abstract; col. 1, lines 21-25; col. 3, lines 6-12 and 19-32; col. 6, lines 30-48; col. 8, lines 46-51). For one type of method and system, the method of the continuous flow assay system generally comprises the steps of 1) flowing the first component into the main

Art Unit: 1639

channel and concurrently flowing the second component into the main channel (refers to instant claimed step (a)); 3) the first and second components in the main channel are able to mix and interact (refers to instant claimed step (b)); 4) flowing a test compound into the main channel; and 5) determining the whether the test compound has an effect on the interaction between the first and second component (see e.g. col. 6, lines 58-67; col. 7, lines 1-16; col. 17, lines 32-55; col. 18, lines 16-37). The first component includes molecules such as receptor or substrate (refers to instant claimed second component and instant claim 15)(see e.g. col. 5, line 6 thru col. 6, line 29; col. 17, lines 31-55). The second component includes molecules such as ligand or substrate (refers to instant claimed first component and instant claim 3)(see e.g. col. 5, line 6 thru col. 6, line 29; col. 17, lines 31-55). The biological system produced by the interaction between the first and second components includes enzyme/substrate interaction or receptor/ligand interaction (refers to instant claimed step (b))(see e.g. col. 6, lines 58-67; col. 12, lines 1-19; col. 7, line 66 thru col. 8, line 13). The flow rate for the first component, second component, and the product of the interaction between the first and second components would produce a steady-state signal such that the level of binding between the first and second components, i.e. product, is compared to the negative and/or positive control (see e.g. col. 8, line 14-22; col. 17, line 56 thru col. 18, line 15; col. 18, line 51 thru col. 19, line 22). For example in the receptor/ligand system, the steady-state signal is the result of both free fluorescent ligand and fluorescent ligand bound to the receptor wherein the bound ligand travel the same flow rate as the receptor while the unbound ligand is traveling more slowly and when the test compound inhibit the receptor-ligand interaction the steady state signal is reduce follow by an increase in the fluorescent signal (refers to instant claimed step (c) and instant claims 221, 22, 24-26)(see e.g. col. 17, line 56 thru col. 18,

Art Unit: 1639

line 15; col. 18, line 51 thru col. 19, line 22; col. 32, line 56 thru col. 33, line 45). The components are flowed using the fluid direction component electrokinetic transport system or micropumps (refers to instant claim 20)(see e.g. col. 10, lines 9-40; col. 19, line 23-28 and 57-58). The main channel is a microchannel (refers to instant claimed first channel and instant claim 23)(see e.g. col. 3, line 39-41; claim 1, line 53-56). The detectable signal comprise labels such as chromogenic or fluorogenic labels (see e.g. col. 12, line 9 thru col. 14, line 67; col. 17, line 12-30).

Additionally, the features of remaining dependent claims (i.e. assay temperature of claims 4-6; concentration of claims 9-12, and 16-19; rate of flow of claims 7, 8, 13 and 14) are either specifically described by the reference (e.g. col. 19, line 57 thru col. 20, line 15), or constitute obvious variations in parameters which are routinely modified in the art (e.g. col. 32, line 56 thru col. 33, line 45), and which have not been described as critical to the practice of the invention.

Therefore, the system and method of Parce et al. anticipates the presently claimed invention.

Conclusion

13. No Claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

Art Unit: 1639

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
November 28, 2005

FOR SCHOOL PERSONNEL
BY EXAMINER